

1636 \$  
PATENT *Shw A1*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of )

Shannon Mitchell )

Serial No. 09/931,506 )

Filing Date: August 16, 2001 )

For: DECELLULARIZED TISSUE ENGINEERED )  
CONSTRUCTS AND TISSUES )

Group Art Unit: 1636

Examiner: D. Sullivan

Docket No. 000250.00025

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Post Office Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

Submitted herewith are two (2) sheets of Form PTO-1449. A copy of each of the references listed therein is enclosed. It is respectfully requested that the Examiner make his/her consideration of each of these documents formally of record.

The Commissioner is authorized to charge \$180.00 to effect entry of this Information Disclosure Statement to Deposit Account 19-0733. Further, the Commissioner is authorized to charge any additional fees which may be required or credit any overpayment to our Deposit Account 19-0733.

Respectfully submitted,

Dated: June 11, 2004

By:

*Sarah A. Kagan*

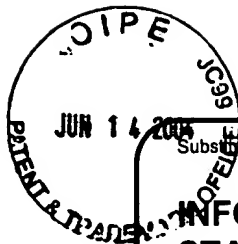
Sarah A. Kagan

Registration No. 32,141

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

**Complete if Known**

Application Number	09/931,506
Filing Date	August 16, 2001
First Named Inventor	Shannon MITCHELL
Art Unit	1636
Examiner Name	D. Sullivan
Attorney Docket Number	000250.00025

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		US-2002/0160001 A1	10/31/2002	Niklason et al.	
		US- 2003/0235562	12/25/2003	Niklason et al.	
		US- D323,895	02/11/1992	Protzmann	
		US- 5,364,756	11/15/1994	Livesey et al.	
		US- 5,622,867	04/22/1997	Livesey et al.	
		US- 5,632,778	05/27/1997	Goldstein	
		US- 5,780,295	07/14/1998	Livesey et al.	
		US-			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		WO 97/08295	03/06/1997			

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

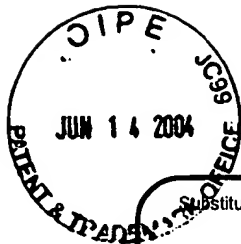
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		ALLISON, S. Dean et al., "Effects of Drying Methods and Additives on Structure and Function of Actin: Mechanisms of Dehydration-Induced Damage and Its Inhibition," <i>Archives of Biochemistry and Biophysics</i> (October 1, 1998), pp. 171-181, Vol. 358, No. 1	
		BEATTIE, Gillian M. et al., "Trehalose: A Cryoprotectant That Enhances Recovery and Preserves Function of Human Pancreatic Islets After Long-Term Storage," <i>Diabetes</i> , (March 1997), pp. 519-523, Vol. 46	
		ELMORE, James R. et al., "Cryopreservation affects endothelial and smooth muscle function of canine autogenous saphenous vein grafts," <i>J. of Vascular Surgery</i> , (May 1991), pp. 584-592, Vol. 13, No. 5	
		FERBER, Dan., "Law-Grown Organs Begin To Take Shape," <i>Science</i> , (April 16, 1999), pp. 422-425, Vol. 284	
		HILES, M.C., et al., "Mechanical properties of xenogeneic small-intestinal submucosal when used as an aortic graft in the dog," <i>J. Biomedical Materials Research</i> , (1995), pp. 883-891, Vol. 29	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO/SB/08a (05-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Sheet 2 of 2

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Examiner Name	D. Sullivan
Attorney Docket Number	000250.00025

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		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		HUYNH, Tam et al., "Remodeling of an acellular collagen graft into a physiologically responsive neovessel," <i>Nature Biotechnology</i> , (November 1999), pp. 1083-1086, Vol. 17	
		NIKLASON, L.E., "Replacement Arteries Made to Order," <i>Science</i> , (November 19, 1999), pp. 1493-1494, Vol. 286	
		RICH, S.J. and ARMITAGE, W.J., "Propane-1,2-diol as a Potential Component of a Vitrification Solution for Corneas," <i>Cryobiology</i> , (1990) pp. 42-54, Vol. 27	

Examiner  
SignatureDate  
Considered

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# FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ ) 180

## Complete If Known

Application Number 09/931,506  
Filing Date August 16, 2001  
First Named Inventor Shannon MITCHELL  
Examiner Name D. Sullivan  
Art Unit 1636  
Attorney Docket No. 000250.00025

## METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money ☐ Other ☐ None  
Order

☒ Deposit Account:

Deposit Account Number 19-0733

Deposit Account Name Banner & Witcoff, LTD.

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments  
☒ Charge any additional fee(s) during the pendency of this application  
☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) (\$ ) 0

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims		Extra Claims	Fee from below	Fee Paid
Independent Claims		0	0	0
Multiple Dependent		0	0	0

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$ ) 0

\*\*or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17 (q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	180
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) \_\_\_\_\_

\*Reduced by Basic Filing Fee Paid SUBTOTAL (3) (\$ ) 180

## SUBMITTED BY

Name (Print/Type) Sarah A. Kagan Registration No. (Attorney/Agent) 32,141 Telephone 202.824.3000  
Signature [Signature] Date June 11, 2004

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